

Appl. No: 09/380,447
Amendment Dated July 7, 2006
Reply to Office Action dated April 7, 2006

REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims in view of the following Remarks.

Claims 3, 4, and 44 have been amended merely for clarification. No new matter is added by the amendments. Claims 29, 48-49, and 52-54 were withdrawn as being directed to a non-elected species. Applicants submit that in the least claim 1 is a linking claim and request rejoinder of the withdrawn claims upon notice of allowability of the linking claim. Claims 1, 3-4, 7-9, 11-12, 29-33, 44-49, and 52-58 are pending in the application.

Interview Summary

Applicants thank the Examiner for the interview on April 5, 2006. We discussed the return of the Office Action of March 9, 2006 as undeliverable. The examiner indicated that she would send out the Office Action again and reset the time.

Information Disclosure Statement

Applicants thank the Examiner for initialing and returning the signed PTO-1449 form originally filed on 02/26/2004.

Withdrawn Rejections

Applicants acknowledge the withdrawal of the rejection of claims 1, 3-4, 7, 9, 11-12, 30-31, and 44 under 35 U.S.C. 102(b) over Light, II et al.

Applicants acknowledge the withdrawal of the rejection of claims 1, 3-4, 7-9, 11-12, 30-33, and 44-47 under 35 U.S.C. 103(a) as obvious over Light II, et al. in view of Marks et al.

Applicants acknowledge that the Examiner has indicated that the elected species is free of the prior art.

35 U.S.C. § 112, first paragraph

Claims 1, 3, 4, 7-9, 11, 12, 30-33, 44-47, and 55-58 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the claims are directed to a broad genus of variants of wild type major coat proteins, but does not identify any core structure that must be conserved. The Examiner states that the claim language limiting the major coat protein to that of a filamentous phage, lambda

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phage, Baculovirus, T4 phage, or T7 phage is insufficient to provide a core structure, because there is a substantial variation among the structure of these major coat proteins. Applicants traverse this rejection.

Applicants note that there is a strong presumption that an adequate written description of the claimed invention exists (*See MPEP 2163.II.A.*), such that "a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption." *MPEP 2163.04*. The determination of whether a specification meets the written description requirement depends upon several factors, including:

- a) partial structure;
- b) physical and/or chemical properties;
- c) functional characteristics;
- d) known or disclosed correlation between structure and function;
- e) method of making.

Applicants respectfully submit that when the above factors are carefully weighed, the specification describes the claimed subject matter in such a way as to reasonably convey to one of skill in the art that Applicants had possession of the claimed invention.

The specification exemplifies the generation of a variant of wild type major coat protein VIII of filamentous phage (see, e.g., Examples 10-12). The specification further explicitly discloses that the wild type major coat proteins of other phage display systems, including lambda phage, T4 phage, T7 phage, and Baculovirus can also be mutated to form variants within the scope of the present invention (page 43, lines 13 through page 44 line 34).

The Examiner asserts that the major coat proteins of viruses lack a "structural nexus." In response, Applicants submit that all of these viruses are well known for being useful to display heterologous polypeptides in phage display systems, such that the identity of major coat proteins suitable for mutation are well known to those of ordinary skill in the art. Indeed, the specification identifies specific examples of suitable major coat proteins of phage display systems other than the exemplified filamentous phage, provides multiple citations to relevant references for these systems, and notes that the structure and location of these major coat proteins are "well known" (see, e.g., page 43, lines 24 through 27; page 43, line 34 through page 44, line 5; and page 44, lines 6-14).

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Applicants also note that for purposes of meeting the requirements for Written Description, "[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." *MPEP 2163*. Since the structure and location of major coat proteins for the claimed phages are well known in the art, Applicants need not explicitly disclose their structure in the specification.

In this regard, the Examiner's attention is respectfully directed to *Falkner vs. Inglis*, (Interference No. 105,187) (Fed. Cir. 2006). In *Falkner*, the specification at issue discussed vaccinia vectors in general, but only provided a detailed example of herpes viruses. The specification asserted that the "invention can be applied to any virus where one or more essential gene(s) can be identified and deleted from or inactivated within the virus genome," even though acknowledging that "[n]o vaccinia virus with a deletion in an essential gene has yet been produced."

Nevertheless, the court held that the specification adequately described the interference count at issue, which was directed to a specific vaccinia vaccine comprised of a poxvirus. The court based its decision on the fact that the skilled person would be able to identify "essential" poxvirus genes from the knowledge in the prior art. The court specifically held that "there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure," and stated that the failure of the specification to reduce a poxvirus vaccine to practice was insufficient to render the vaccine inadequately described. Consequently, Applicants submit that the present specification need not identify any "core structure" of the wild type major coat proteins recited by the claims.

Moreover, the Applicants have provided guidance in selecting portions of the major coat protein for mutation according to the present invention. The specification provides a table listing preferred residues for substitution at preferred locations for M13, fl, and fd coat protein VIII (page 41, line 25 through page 42, line 16). The specification discloses the surprising discovery that "a large number of alterations to phage major coat proteins are possible and tolerated, while retaining the ability to display polypeptides on the phage surface" (page 45, lines 33-35). Indeed, the specification also discloses and exemplifies the generation of, and screening for, useful variant coat proteins of the invention using phage display technology (page 44, line 35 through page 49, line 29; and Examples 3-4).

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The Applicants respectfully submit that in light of: 1) the specification's disclosure of multiple phage display systems useful in the present invention as well as multiple citations to references concerning the use of these systems, 2) the fact that the major coat protein structures and locations of multiple phages are well known in the art, 3) the specification's disclosure of preferred major coat proteins of preferred phage systems and of specific preferred mutations of phage coat protein VIII in various filamentous phages, and 4) the disclosure of methods for generating and screening for useful variant major coat proteins, the working examples are well representative of the claimed genus of variant major coat proteins. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. § 112, second paragraph

Claims 3-4 and 44 were rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for alleged vagueness and lack of antecedent basis. These claims have been amended merely for clarification and to provide proper antecedent basis. Withdrawal of the rejection is therefore requested.

35 U.S.C. § 102

Claims 8, 9, 11, 12, 30, 46, and 47 were rejected under 35 U.S.C. § 102 as anticipated by Larocca et al. (U.S. Patent 6,451,527 B1).

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *MPEP 2131* (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

The Applicants respectfully submit that Larocca et al. does not anticipate the present claims, because the effective filing date of this reference is subsequent to that of the present application with respect to the disclosure of variants of wild type major coat proteins. The filing date of Larocca et al. is February 26, 1999. Larocca claims priority to 09/193,445 (filed November 17, 1998) as a continuation-in-part, which in turns claims priority to 09/195,379 (filed November 17, 1998) as a continuation-in-part, which itself is a continuation-in-part of 09/141,631 (filed August 28, 1998 and now abandoned).

Applicants respectfully submit, however, that the priority application US Ser. No. 09/141,631 of Larocca et al. do not disclose fusion proteins comprising a heterologous

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polypeptide fused to at least a portion of a variant of a wild type major coat protein of a virus that is a filamentous phage, lambda phage, Baculovirus, T4 phage, or T7 phage, as required by the present claims. In particular, the priority application does not disclose the mutant filamentous phage coat protein VIII disclosed in Larocca et al., which the Examiner alleges is found in the disclosure that anticipates the present claims. Consequently, the Applicants respectfully submit that Larocca et al. is not entitled to a priority date of August 28, 1998.

In contrast, and as the Examiner acknowledges on page 4 of the Office Action, the present claims are entitled to the benefit of priority of 60/103,514 (filed October 8, 1998), and 60/134,870 (filed May 19, 1999). Therefore, the effective filing date of the present application antedates the effective filing date of Larocca et al. with respect to the subject matter of the present claims.

For the foregoing reasons, Applicants respectfully submit the present claims are patentable over Larocca et al., and withdrawal of the rejection is therefore requested.

35 U.S.C. § 103

Claims 1, 3, 8, 9, 11, 12, 30-32, 44, 46, and 47 were rejected under 35 U.S.C. §103(a) as obvious over Light, II et al. (U.S. Patent 5, 770,356) in view of Larocca et al. (U.S. Patent 6,451,527 B1).

In order to establish a *prima facie* case of obviousness, three basic criteria must be met, namely: (1) the references must teach or suggest all of the claim limitations; (2) there must be a suggestion or motivation, either in the references or in the knowledge generally available to one of skill in the art, to modify the references to have all of the claim limitations; and (3) there must be a reasonable expectation of success. Applicants submit that not all of these requirements have been met, because the references do not suggest all of the claim limitations, there is no suggestion or motivation to combine or modify the references to disclose all of the claim limitations, and because there is no reasonable expectation of success.

The Applicants submit, and the Examiner has acknowledged, that Light II et al. fails to disclose a variant major coat protein. The Examiner contends, however, that Larocca et al. remedies this deficiency. Applicants traverse this rejection.

As discussed above, Larocca et al. is not prior art against the present application with respect to a heterologous polypeptide fused to a variant of a wild type major coat protein as

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recited by the present claims, because the effective filing date of the present application antedates any disclosure of variant major coat proteins by the priority application of Larocca et al. Thus, Applicants respectfully request withdrawal of this rejection.

Claims 1, 7-9, 11, 12, 30-32, 46, 47, 55, and 58 were rejected under 35 U.S.C. 103(a) as obvious over Larocca et al. (U.S. Patent 6,451,527 B1) in view of Li et al. (J. Biol. Chem., 1993). Applicants traverse this rejection.

The Applicants submit that Larocca et al. is not prior art against the present claims for the same reasons discussed above. Furthermore, the addition of Li et al. fails to remedy this deficiency. Li et al. discloses mutant M13 major coat proteins, but nowhere teaches or suggests a fusion protein as claimed, comprising a heterologous polypeptide fused to at least a portion of a variant of a wild type major coat protein of a virus selected from the group consisting of a filamentous phage, a lambda phage, a Baculovirus, a T4 phage and a T7 phage.

Withdrawal of the rejection is therefore requested.

Interview Request

Applicants request an interview with the examiner and her supervisor upon receipt of these papers.

SUMMARY

Applicants submit that the claims are in condition for allowance, and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative if prosecution may be assisted thereby.

Respectfully submitted,

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